

**REMARKS/ARGUMENTS*****Claim Status***

Claims 1-20 were subject to the Examiner's rejection(s) the 1<sup>st</sup> Non-Final Office Action dated 2008-07-07 ("1NFOA"), p. 1. Claims 1-13, and 17-20, have been cancelled herein. Claims 14-16 are currently amended and remain. Claim 21 is new.

***Specification***

The Examiner requested clarification of the priority claim. (1NFOA, p. 2) Applicant claims benefit of both the PCT and U.S. applications. In the specification, paragraph 001 been amended to clarify the priority claim. This application is a National Stage of PCT/US04/43760 which claims priority to US Provisional Application Number 60/531,266, and also a continuation in part of Application No. 10/676,459, filed on September 30, 2003, which is a continuation in part of U.S. Patent Application No. 09/655,598 filed on September 5, 2000, now abandoned, which claims benefit of United States Provisional Application number 60/152,468, filed on September 3, 1999.

***Claim Objections***

The Examiner objected to claims 4, 7, and 17. Applicant has cancelled the claims.

***Claim Rejections******35 U.S.C. § 112 - 2nd Paragraph***

Claims 3, 4, 6-9, 12, 14, and 18-20 were rejected under 35 USC § 112, 2nd paragraph. All but claim 14 has been cancelled by the Applicant's amendments filed herewith. And, the term "elderly", which the Examiner considered "unclear" (1NFOA, p. 3, ¶ 14), has been deleted from claim 14. Withdrawal of the rejection is requested.

Applicant notes that the specification teaches use of a Lepidium extract capable of enhanced production of Chondrocyte IGF-1. (Spec., ¶¶ 27, 28, Fig. 2) Particularly, treatment with the Applicant's Maca extracts (SPI 249 and SPI 250) produced sustained IGF-1 production in human chondrocytes. (Id.)

***35 U.S.C. § 112 – 1st Paragraph***

The Examiner rejected claims 3, 4, 7, and 8 under 35 USC § 112, 1st paragraph. (1NFOA, ¶ 11, p. 4) The Examiner alleges that undue experimentation would be required to practice the invention as claimed. (Id., ¶ 11, pp. 4-5) The Applicant disagrees - no experimentation would be required. The Axtell<sup>1</sup> article cited by the Examiner supports that the process described by the Applicant would work as described to produce the extract.

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<sup>1</sup> Minor Oil Crops; Part III: Minor essential oil crops - section II: "Distillation of essential oils" (1992) FAO Agricultural Services Bulletin, no. 94 ("Axtell")

The specification describes an extract comprising polar and non-lipidic components of plant material of species Lepidium, family Brassicaceae and uses. (Spec. ¶¶ 11-12) In either extraction process, Lepidium species plant material is exposed to steam and the condensate collected and reduced by drying. (Id., ¶¶ 22, 24)

Likewise, the Axtell article describes a process of distilling essential oils from plant material using a water/steam or steam distillation process. (Axtell, p. 2) The exposure of plant material to steam results in a mixture of water and essential oil, which will separate into oil and water layers and is easily separable. (Id. p. 3) Given the teachings of the Applicant's specification regarding the desirability of a purposeful separation of the aqueous and lipidic fractions of a steam distillate of Lepidium plant material to concentrate the polar components by at least 75% (Spec., ¶¶ 8, 12, and 18), a person of ordinary skill in the art would apply the teachings of Axtell to identify and identify and separate the lipidic and aqueous fractions of a steam distillate of Lepidium plant material to create the Applicant's extract. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a patent need not disclose that which is well known in the art). No experimentation would be necessary to practice the Applicant's invention.

***35 U.S.C. § 102******(US 6,267,995 issued to Zheng (“Zheng ‘995”))***

The Examiner has rejected claims 1, 2, 5, 6 and 9-20 based on Zheng ‘995. (1NFOA, pp. 5-6) Applicant has amended claims 14-16 and cancelled all other claims.

Applicant notes it is entitled to benefit from its provisional application no. 60/152, 468, filed in September 1999 and that Zheng ‘995 is not prior art. (Spec. ¶ 1). Applicant also agrees that Zheng ‘995 does not teach that the composition has the same effects on the body as those claimed by the Applicant. (Id. p. 6) Still, the Applicant’s claims are now directed at an extract possible of a specific and sustained enhanced production of Chondrocyte IGF-1. (Claims 14-16), and a method of treating cartilage degradation. (Claim 21) Zheng ‘995 fails to teach either an extract capable of Chondrocyte IGF-1 production or a method of using the extract to treat cartilage degradation by enhancing production of Chondrocyte IGF-1 and thus fails to anticipate the Applicant’s claims.<sup>2</sup>

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<sup>2</sup> See *Xerox Corp. v. 3Com Corp.*, 458 F.3d 1310, 1322 (Fed. Cir. 2006) (Every element of the claimed invention must be described in a single prior art document).

***Claim Rejections - 35 U.S.C. § 103***

The Examiner rejected claims 1, 6, and 9, over Zheng '995. (1NFOA, ¶ 13, pp. 6-7) The Applicant reiterates its previous argument: Zheng '995 is not prior art and fails to disclose all the elements of the Applicant's claimed invention. Zheng '995 is not modifiable to render the claimed subject matter.

***Conclusion***

The Assignee believes it has responded to all the issues raised by the Examiner's Office Action.

Respectfully submitted,

Venable, Campillo, Logan, & Meaney P.C.

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By: /Michael F. Campillo/  
Michael F. Campillo, Reg. No. 44583

Attorneys for Applicant  
1938 E. Osborn Rd.  
Phoenix, Arizona 85016  
(602) 631-9100